Stroke and Medical Devices

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Treatments

Pharmacotherapy Medical Devices

Regulatory Decision Points

Medical Device Classification

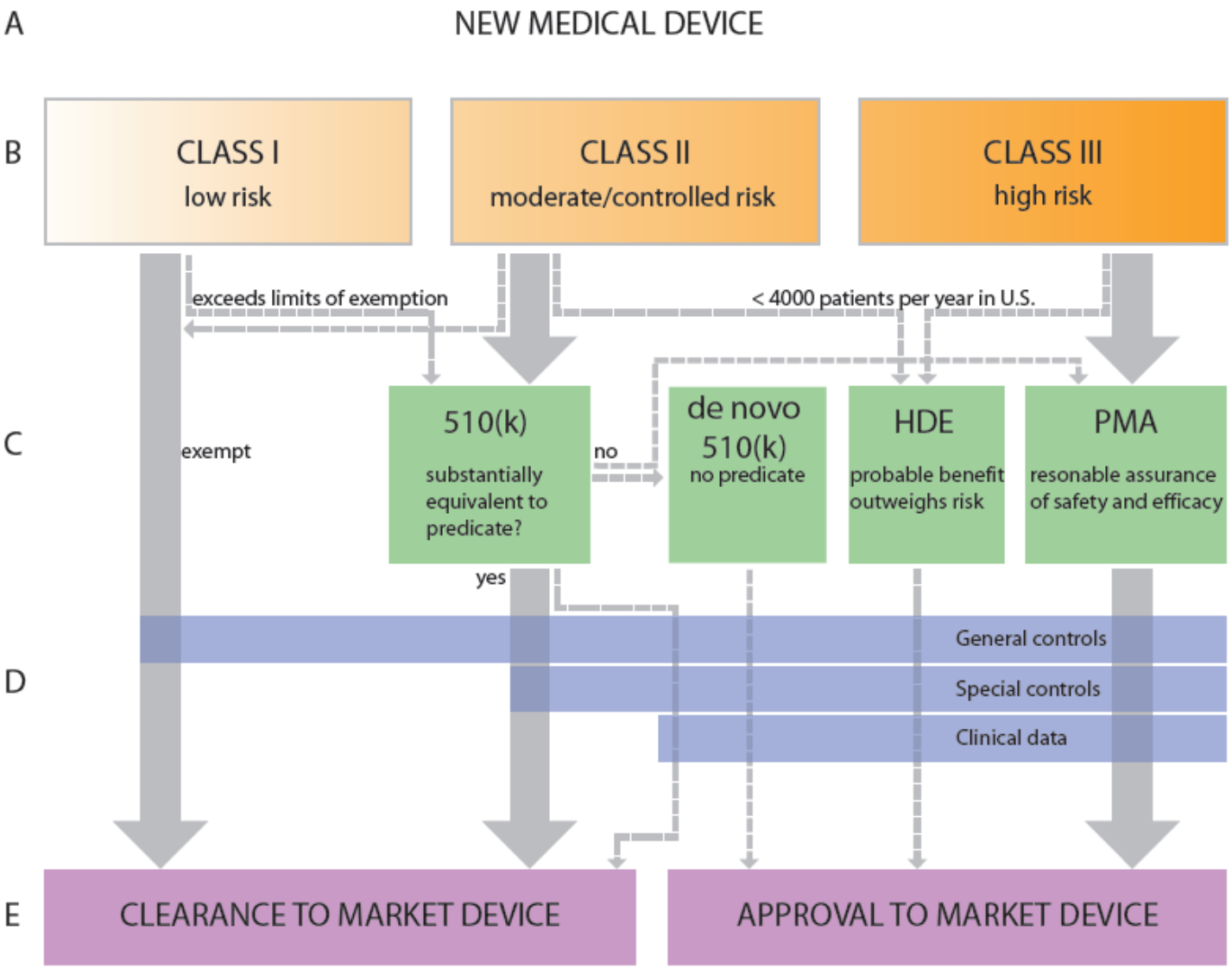
Benefit Risk Assessment

Predicate Devices

Valid Scientific Evidence

Least Burdensome Approach

Current State of Review



When is Clinical Data Needed?

- PMA: almost always needed
- De novo: typically needed, but not always
- 510(k): generally not needed

You can request feedback on any protocols through the pre-submission process, preferably before starting the study

Experience in Moving Neurological Medical Devices From **Bench to Market**

Clot Retriever for Ischemic Stroke

Epilepsy DBS

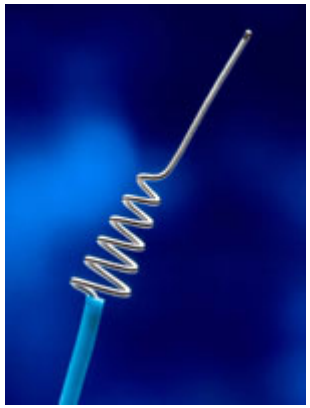
ADHD Neurodiagnostics

DEKA Prosthetic Arm

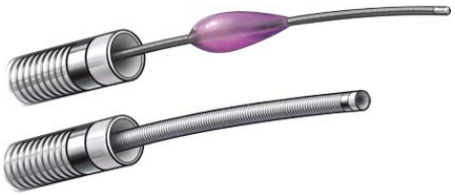
Cefaly Medical Device For Migraine

Microcatheters for the neurovasculature

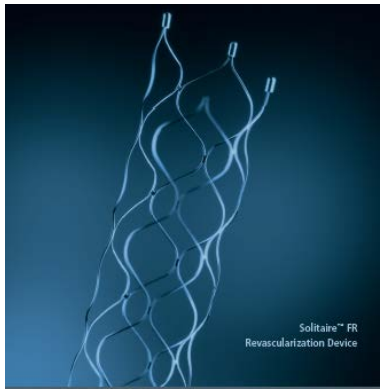
Cleared Mechanical Neurothrombectomy (Clot Retrieval) Devices



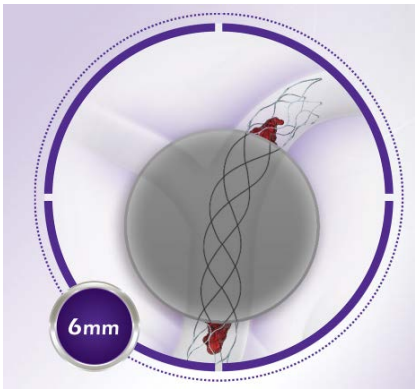
MERCI Retriever



Penumbra Reperfusion System



Medtronic/Covidien Solitaire Revascularization Device

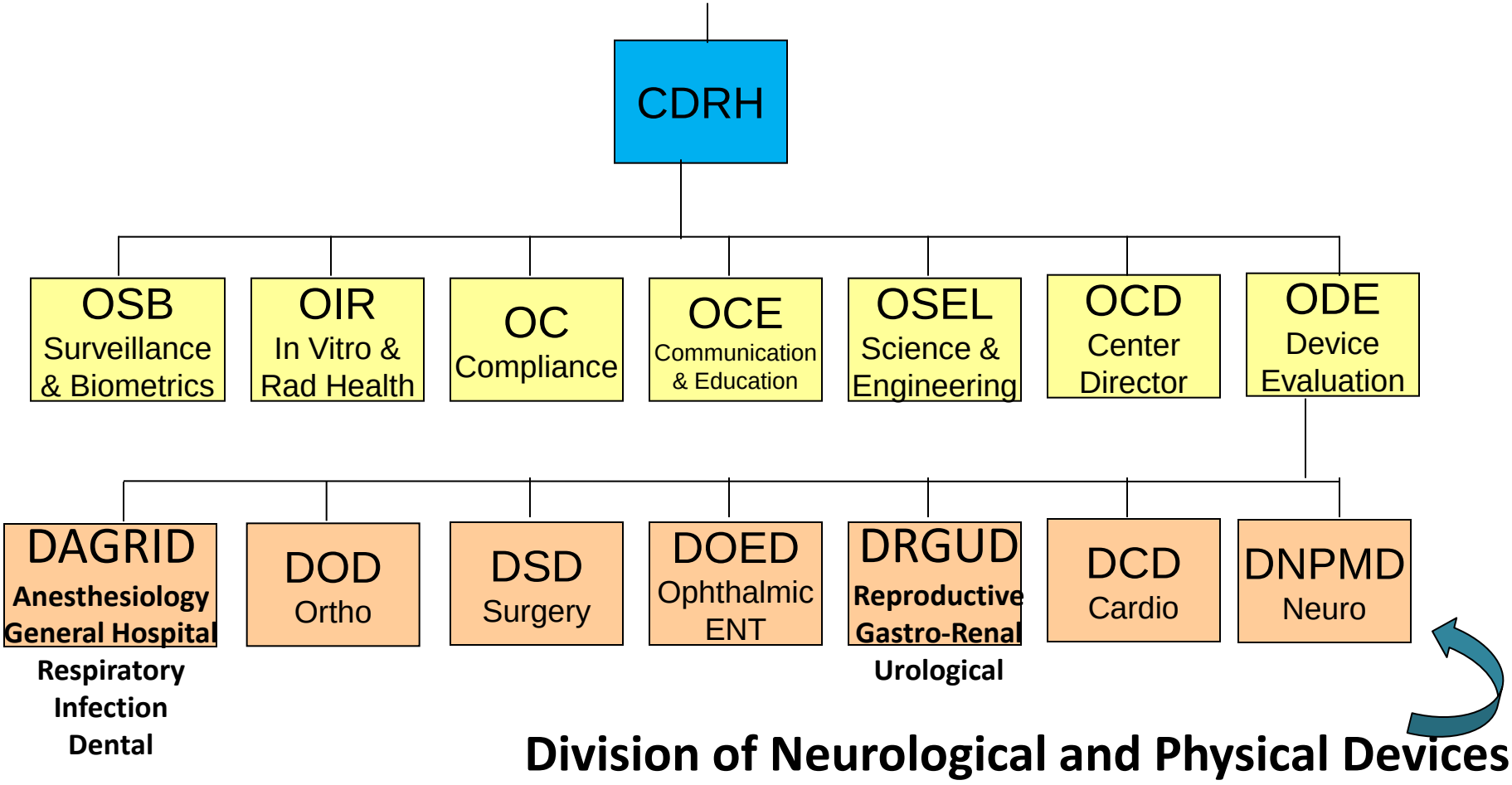


Stryker Neurovascular Trevo ProVue Retriever

Intended Use: Restoring blood flow or revascularization in intracranial vessels within 8 hours of acute ischemic stroke symptom onset. For patients who are ineligible to receive or who failed intravenous tissue plasminogen activator (IV t-PA).

Center for Devices and Radiological Health (CDRH) Organization

Pathway for Neurological and Physical Medicine Regulatory Submissions



Neurothrombectomy Guidance

Guidance for Industry and FDA Staff

Pre-Clinical and Clinical Studies for Neurothrombectomy Devices

Document issued on: June 18, 2007

Guidance Topic Areas

Biocompatibility

Pre-Clinical Evaluation

Bench Testing

Animal Testing

Clinical Studies

Measures of Success

Alternate Sources of Clinical Info

Meeting Goals-Devices

4 Topic Areas

Clinical Study Design, Patient Groups

Clinical Outcomes, Imaging, Safety

Statistical Considerations

Registries

Closing Thoughts